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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,594	11/21/2005	Erik Flaxmeier	26317-00006	4474

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EXAMINER	
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ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,594	FLAXMEIER ET AL.	
	Examiner	Art Unit	
	SAMANTHA GOOD	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,29 and 30* is/are pending in the application.

4a) Of the above claim(s) *13-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 29-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 25, 2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rusk et al (5,681,280).

Referring to claim 1, Rusk et al teaches a spreader structure (Figure 2) for insertion into a hollow organ (Col. 3, lines 20-32 and Col. 7, lines 16-24), said spreader structure comprising an elongated body (14) having a circumference and a longitudinal axis (Col. 6, lines 4-8; Figure 2); a first connecting section (16) located at one end of the elongated body (14) (Col. 6, lines 30-34; Figure 2); a second connecting section (24) located at a second end of the elongated body (14) opposite the first connecting section (16) (Col. 6, lines 9-13 and Col. 9, lines 46-52; Figure 2); a plurality of spreader rods (18/20) radiating from the first connecting section (16), extending substantially along the longitudinal axis of said elongated body to the second connecting section (24), and distributed over the circumference of the elongated body and wherein the spreader rods are positionable against a wall of the hollow organ by means of radial expansion (Col. 6, lines 22-33 and Col. 7, lines 12-25; Figure 2), wherein said spreader rods (18/20) contain a non-linear segment (72) having substantially alternating curved sections at its inner surface when in a collapsed state (Col. 8, line 65 through Col. 9, line 4; shown best in Figures 4 and 9); and at least one are of said spreader rods (18/20) along the longitudinal axis having reduced flexural stiffness in comparison to adjacent areas thereto (Col. 8 line 60 through Col. 9 line 7 and Col. 11, lines 1-12).

Rusk et al teaches that each spreader rod contains a non-linear segment having substantially alternating curved section at its inner surface when in a collapsed state (clearly shown in Figure 4), however fails to expressly teach having a substantially alternating curved section at its outer surface when in a collapsed state. The instant application teaches that the spreader rods contain a non-linear segment having

substantially alternating curved sections in order to allow for the spreader rod to have reduced flexural stiffness (paragraphs 0045, 0046 of the printed publication) so that these sections can be deformed particularly easily and at the same time particularly strong during the deformation while the substantially straight and relatively sturdy sections 20 and 24 are barely deformed (paragraph 0053). The instant specification fails to teach any criticality or unexpected result from having the spreader rods contain a non-linear segment having substantially alternating curved sections at its outer surface. Furthermore, in paragraph 0017 of the instant application teaches that in order for the spreader rod to have reduced flexural stiffness the shape of the structure could be either a meander-shaped structure or can be flat or, as in the present case, it can preferably be the surface shell of a circular cylinder. This further demonstrates that there is a lack of disclosed criticality and unexpected result for having the non-linear segment having substantially alternating curved sections at its outer surface. Rusk teaches that the spreader rods contain a non-linear segment having substantially alternating curved section at its inner surface in a collapsed state, and similarly teaches having this configuration in order to provide reduced flexural stiffness wherein the surrounding sections are substantially straight and relatively sturdy (Col. 8, line 65 through Col. 9, line 4; shown in Figures 2-4 and 9). Due to a lack of disclosed criticality and unexpected result, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the spreader rods containing a non-linear segment having substantially alternating curved sections at its inner surface, as taught by Rusk et al, to also have a non-linear segment having substantially alternating curved sections

at its outer surface because this is a change in shape, which is a matter of choice (See MPEP 2144.04). Furthermore, due to a lack of disclosed criticality and unexpected result, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the spreader rods containing a non-linear segment having substantially alternating curved sections at its inner surface, as taught by Rusk et al, to also have a non-linear segment having substantially alternating curved sections at its outer surface because it would be obvious to try since there are a finite number of identified, predictable solutions with a reasonable expectation of success since the alternating curved sections can only be applied to a finite number of surfaces on the spreader rod.

Referring to claim 2, Rusk et al teaches a spreader structure according to claim 1, wherein the at least one area (72) having reduced flexural stiffness has a reduced cross sectional area (Col. 8 line 60 through Col. 9 line 7 and Col. 11, lines 1-12; Figures 2, 3, and 5).

Referring to claim 3, Rusk et al teaches a spreader structure according to claim 1, wherein the at least one area (72) having reduced flexural stiffness has a non-linear rod section (seen best in Figure 5).

Referring to claim 4, Rusk et al teaches a spreader structure according to claim 1, wherein the at least one area (72) having reduced flexural stiffness has a meander-

shaped rod section(Col. 8 line 60 through Col. 9 line 7 and Col. 11, lines 1-12; seen best in Figure 5).

Referring to claim 5, Rusk et al teaches a spreader structure according to claim 1, wherein the at least one area (72) having reduced flexural stiffness has a wave-shaped rod section (Col. 8 line 60 through Col. 9 line 7 and Col. 11, lines 1-12; seen best in Figure 5).

Referring to claim 6, Rusk et al teaches a spreader structure according to claim 1, wherein the at least one area (72) having reduced flexural stiffness has a zigzag-shaped rod section (Col. 8 line 60 through Col. 9 line 7 and Col. 11, lines 1-12; seen best in Figure 5).

Referring to claim 7, Rusk et al teaches a spreader structure according to claim 1, wherein the at least one area (72) having reduced flexural stiffness has a square cross section (Col. 8 line 60 through Col. 9 line 7 and Col. 11, lines 1-12; seen best in Figure 2).

Referring to claim 8, Rusk et al teaches a spreader structure according to claim 1, wherein the first (16) and second (24) connecting sections are designed as central hubs of the spreader rods (18/20) in the area of the longitudinal axis (Col. 6, lines 5-47; seen best in Figure 1).

Referring to claim 9, Rusk et al teaches a spreader structure according to claim 1, wherein the first connecting section (16) has an opening (82) through which a central rod (26 with sheaths 98, 96 and 92) can be slid through to the other connecting section (24) (Col. 9, line 38 through Col. 10, line 20) (Figures 2-5). Rusk et al teaches that the second connection section (24) includes a projecting mounting stem 86 having an axial bore 88 for receipt of the distal tip of the deployment mandrel, the mandrel being affixed therein by crimping, soldering, brazing or other means (Col. 9, lines 46-52).

Referring to claim 10, Rusk et al teaches a spreader structure according to claim 1, wherein the first (16) and second (24) connecting sections are substantially cylindrical (Figures 2-5).

Referring to claim 11, Rusk et al teaches a spreader structure according to claim 1, wherein each of the spreader rods (18/20), starting from the first connecting section, has a first section that radially curves outward as well as a subsequent substantially straight second section (Col. 7, lines 36-50; Figures 2-3 and 5).

Referring to claim 29, Rusk et al teaches a method of using a spreader structure (Figure 2) for insertion into a hollow organ (Col. 3, lines 20-32 and Col. 7, lines 16-24), the method comprising: providing an elongated body (14) having a plurality of spreader rods (18/20) extending evenly from around the elongated body (Col. 6, lines 4-8),

wherein the spreader rods (18/20) each have at least one area (72) of reduced flexural stiffness in comparison to adjacent areas (Col. 8 line 60 through Col. 9 line 7 and Col. 11, lines 1-12; Figures 2, 3, and 5), further wherein said spreader rods (18/20) contain a non-linear segment (72) having substantially alternating curved sections at its inner surface when in a collapsed state (Col. 8, line 65 through Col. 9, line 4; shown best in Figures 4 and 9); positioning the elongated body (16) on a spreader device (distal end) (Figures 1 – 5); inserting the elongated body and spreader device into the hollow organ while the elongated body is at least partially compressed (Figure 1); and expanding the elongated body (Col. 7, lines 12-25; Figure 2).

Rusk et al teaches that each spreader rod contains a non-linear segment having substantially alternating curved section at its inner surface when in a collapsed state (clearly shown in Figure 4), however fails to expressly teach having a substantially alternating curved section at its outer surface when in a collapsed state. The instant application teaches that the spreader rods contain a non-linear segment having substantially alternating curved sections in order to allow for the spreader rod to have reduced flexural stiffness (paragraphs 0045, 0046 of the printed publication) so that these sections can be deformed particularly easily and at the same time particularly strong during the deformation while the substantially straight and relatively sturdy sections 20 and 24 are barely deformed (paragraph 0053). The instant specification fails to teach any criticality or unexpected result from having the spreader rods contain a non-linear segment having substantially alternating curved sections at its outer surface. Furthermore, in paragraph 0017 of the instant application teaches that in order for the

spreader rod to have reduced flexural stiffness the shape of the structure could be either a meander-shaped structure or can be flat or, as in the present case, it can preferably be the surface shell of a circular cylinder. This further demonstrates that there is a lack of disclosed criticality and unexpected result for having the non-linear segment having substantially alternating curved sections at its outer surface. Rusk teaches that the spreader rods contain a non-linear segment having substantially alternating curved section at its inner surface in a collapsed state, and similarly teaches having this configuration in order to provide reduced flexural stiffness wherein the surrounding sections are substantially straight and relatively sturdy (Col. 8, line 65 through Col. 9, line 4; shown in Figures 2-4 and 9). Due to a lack of disclosed criticality and unexpected result, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the spreader rods containing a non-linear segment having substantially alternating curved sections at its inner surface, as taught by Rusk et al, to also have a non-linear segment having substantially alternating curved sections at its outer surface because this is a change in shape, which is a matter of choice (See MPEP 2144.04). Furthermore, due to a lack of disclosed criticality and unexpected result, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the spreader rods containing a non-linear segment having substantially alternating curved sections at its inner surface, as taught by Rusk et al, to also have a non-linear segment having substantially alternating curved sections at its outer surface because it would be obvious to try since there are a finite number of identified, predictable solutions with a reasonable expectation of success since the

alternating curved sections can only be applied to a finite number of surfaces on the spreader rod.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rusk et al (5,681,280).

Referring to claim 12, Rusk et al teaches having a plurality of spreader rods (18/20) however fails to expressly teach having six spreader rods. In absence of any disclosed criticality or unexpected result, it would have been obvious to one of ordinary skill in the art at the time that the invention was made to have the plurality of spreader rods, as taught by Rusk et al, to be six because this is a duplication of parts that would be have been obvious to one of ordinary skill in the art (See MPEP 2144.04).

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rusk et al (5,681,280) in view of Tu et al (6,319,251).

Referring to claim 30, Rusk et al fails to expressly teach placing the elongated body (14) within a sheath. Tu et al teaches an analogous method of using a spreader structure for insertion into a hollow organ (Col. 9, line 64 through Col. 10, line 4). Tu et al teaches providing an elongated body (21) having a plurality of spreader rods (4I, 4J, 4K, 4L) extending evenly from around the elongated body (21) (Col. 7, lines 35-60; Figure 4), placing the elongated body (21) inside a sheath (11) while being at least partially compressed (Col. 6, lines 64-67); inserting the sheath (11) into the hollow organ; ejecting the elongated body (21) from the sheath (100); and expanding the elongated body (Col. 9 line 64 through Col. 10, line 4; Figures 3 and 4). It would have

been obvious to one of ordinary skill in the art at the time of the invention to modify the elongated body having a plurality of spreader rods, as taught by Rusk et al, to be placed inside a sheath while being at least partially compressed, inserting the sheath into the hollow organ, ejecting the elongated body from the sheath and expanding the elongated body, as taught by Tu et al, in order to allow for ease of deployment using a push-pull controller (Col. 9, lines 12-15) and for ease of inserting the medical device through an artery or a vein (Col. 9, lines 65-66).

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMANTHA GOOD whose telephone number is (571)270-7480. The examiner can normally be reached on Monday - Friday 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAMANTHA GOOD/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739